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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,826	11/19/2003	J. Donald Hill	018880.0149	3645

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BAKER BOTTS LLP  
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WASHINGTON, DC 20004-2400

EXAMINER
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EREZO, DARWIN P

ART UNIT	PAPER NUMBER
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3773

NOTIFICATION DATE	DELIVERY MODE
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07/22/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/715,826	<b>Applicant(s)</b> HILL ET AL.	
	<b>Examiner</b> Darwin P. Erez	<b>Art Unit</b> 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 May 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 23-25, 27-33 and 67-69 is/are pending in the application.
- 4a) Of the above claim(s) 23-25 and 27-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 67-69 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

1. This Office action is in response to the applicant's communication filed on 5/3/10.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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5. Claims 1-3, 5-8, 12, 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2005/0192604 to Carson et al. in view of US 2002/0161383 to Akin et al., and US 5,456,714 to Owen; and in further view of US 5,904,697 to Gifford et al.

Regarding claim 1, Carson discloses a coupler comprising:

a saddle **14** having a longitudinal axis extending along a first direction (see Fig. 1A);

a channel **32** extending from a first end to a second end, the first end connected to said saddle and a second end having a substantially circular cross-section;

a tissue clamp **16** positioned around the channel, the tissue clamp comprising a clamping portion extending from the base (see figure below), and a connecting portion configured to connect said clamping portion to said channel and limit the axial position of the clamping portion in an unclamped position relative to the saddle (see figure below; note that the distal most ratchet groove 38 is being viewed as the connecting portion, which is fully capable of holding and limiting the axial movement of the clamping portion in an unclamped position, i.e., when the distal groove most 38 first engages the first proximal teeth 34, the tissue clamp does not exert force towards the saddle but will maintain said tissue clamp on the saddle); and a

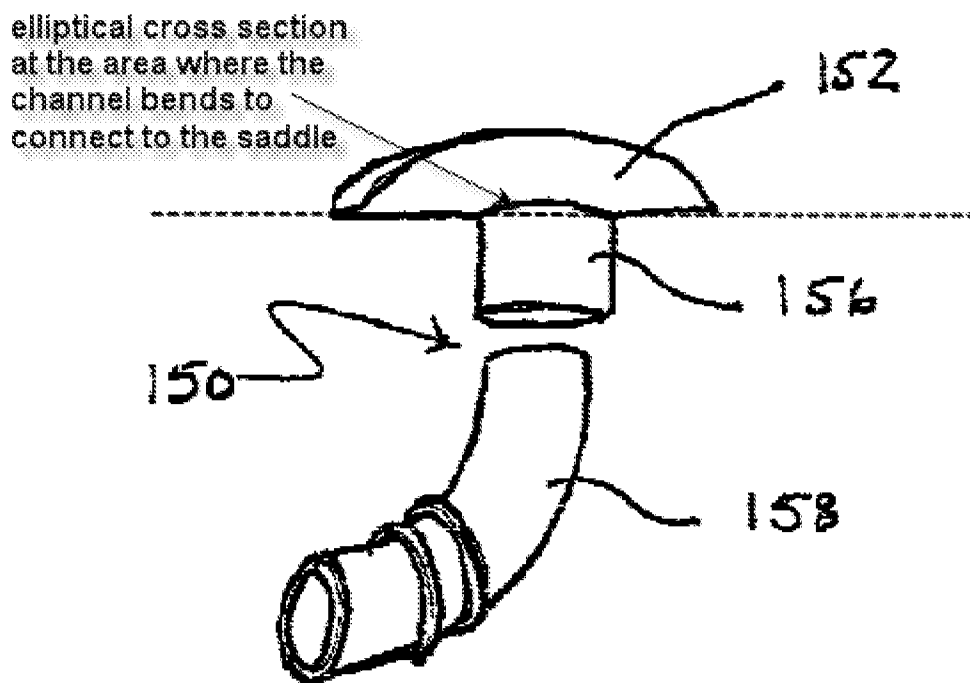
a flange 34 formed at the second end of the channel.



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of Akin. The modified device of Carson would work similar to the device of Akin, thus providing predictable results to the skilled artisan. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82 USPQ2d 1385, 1396 (2007).

Note that the modification to Carson's device to have the channel extend substantially from the saddle will also modify the connection of the channel to the saddle. The modification would follow the teachings of Akin, which discloses that the channel will have an elliptical cross section at the connection to the saddle, as shown in the attached figure below.

**FIG. 13**

Carson also fails to teach that the tissue clamp is configured to elastically move from a clamped position substantially corresponding to a shape of said saddle to an unclamped position not corresponding to the shape of the saddle. Instead, the tissue clamp of Carson is always configured to the shape of the saddle in both deployed and undeployed state.

However, using a tissue clamp that is elastically deformable is well known in the art. Owen discloses a tissue coupler also comprising a tissue clamp 4, wherein the tissue clamp has an unclamped position not corresponding to the shape of flange element 2, and a clamped position that is deformed to correspond to the shape of the flange element 2 within the blood vessel (see Figs. 5 and 6). Therefore, it would have been obvious to one of ordinary skill in the art at time the invention was made to make the tissue clamp of Carson to be elastically deformable, as taught by Owen, because it would allow the tissue clamp to conform to the shape of the saddle and any tissue that is clamped between the saddle and the tissue clamp.

The above combination is also silent with regards to the elliptical cross-section having a first width that is greater than a second width defined by circular cross-section. However, having a portion of a connector flare out to a larger diameter is well known in anastomosis art. For example, Gifford discloses in Fig. 21A a connector 251 that has an end portion that flares out such that the end portion has a width that is greater than remaining portion of the connector. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to taper the channel in order

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to have a larger cross-section for the end portion as it would allow better flow of blood into the blood vessel.

Regarding claims 2, 3, & 12, Carson discloses tissue clamp comprises a shape-memory alloy, and that shape memory alloy comprises a nickel titanium, also known as nitinol (para.0079).

Regarding claim 5, Carson discloses the tissue clamp comprising a plurality of dimpled holes formed there through (fig. 9A, 9B).

Regarding claim 6, Carson discloses the cross-sectional area of said channel's inner surface to be substantially constant as said channel transitions from said first end to said second end (lumen of channel 32).

Regarding claim 7, Carson discloses the cross-sectional area of said channel increases or decreases as said channel transitions from said first end to said second end (exterior of channel , fig. 3C).

Regarding claim 8, Carson discloses a mating surface formed adjacent to said flange (in between flanges 34, fig. 3D).



Regarding claim 68 and 69, the saddle of Carson is designed to be used within a human being, which is normally at 37 degrees Celsius, which covers the recited range recited in the range. Thus, it would be obvious to one of ordinary skill in the art to use a material for the saddle that would remain rigid the recited temperature range.

6. Claims 4, 9 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al., Akin et al., Owen, and Gifford et al., as applied to the rejections to claim 1 above, and in further view of WO 00/24339 to Berreklouw.

Regarding claim 4, the modified device of Carson discloses a tissue clamp, but does not expressly disclose teeth along the periphery of the clamp. Berreklouw teaches a tissue clamp (45, fig. 8) with teeth (26, fig. 8) along the perimeter of the tissue clamp. This arrangement has the apparent advantage of ensuring better connection between the tissue clamp and the vessel. Therefore, it would have been obvious to a person of ordinary skill in the art to modify the tissue clamp of Carson to include teeth, as taught by Berreklouw to obtain the same advantage.

Regarding claims 9 and 67, the modified device of Carson discloses a tissue clamp, but fails to expressly teach a pair of legs on the tissue clamp. However, Berreklouw teaches another embodiment of a tissue clamp (115, fig. 5) with a pair of legs (114, fig. 5) which can be extended and positioned accordingly to another part of the anastomosis device (K, fig. 4) to create adequate clamping force. Therefore, it would have been obvious to a person of ordinary skill in the art to modify the tissue clamp of Carson to include legs as taught by Berreklouw in order to have the tissue clamped adequately to the saddle. Note that modifying the tissue clamp of Carson to

have the pair of legs taught by Berreklouw will have the legs be connected to the flange 34 via grooves 38.

7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al., Akin et al., Owen, and Gifford et al., as applied to the rejections to claim 1 above, and in further view of US 6,814,750 to Kavteladze et al.

The modified device of Carson discloses the claimed invention except that the material is made from a material having an austenitic temperature below 10 degrees Celsius. However, Kavteladze discloses that the transformation temperature of austenitic state nickel titanium alloy is below the normal temperature of a human body (co1.10, lines 43-48), which would allow the material to exhibit relatively high tensile strength and be stable. Below ten degrees includes the range below body temperature, hence, since the tissue clamp disclosed by Carson is made from nickel titanium, the tissue clamp would also exhibit the property of having an austenitic transition temperature below 10 degrees Celsius. Therefore, it would be obvious to a person of ordinary skill in the art, at the time of the invention, that the nickel titanium tissue clamp disclosed by Carson can be modified as taught by Kavteladze to exhibit the same advantage stated above.

8. Claims 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson et al., Akin et al., Owen, and Gifford et al., as applied to the rejections to claim 1 above, and in further view of US 6,554,848 to Boylan et al.

The modified device of Carson discloses the invention substantially as claimed above. Carson does not disclose that the material has an austenitic temperature equal

to or greater than body temperature. Boylan, however, discloses making a device implantable within the body with a nickel titanium alloy having an austenitic phase above body temperature, or 37 degrees Celsius (claim 14), which would allow the material to exhibit relatively high tensile strength and be stable. Therefore, it would have been obvious to a person of ordinary skill in the art, at the time of the invention, that the nickel titanium tissue clamp disclosed by Carson is modified as taught by Boylan to obtain the same advantage.

### ***Response to Arguments***

9. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezzo/  
Primary Examiner, Art Unit 3773